UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

UNITED STATES OF AMERICA and THE STATE OF INDIANA, Plaintiffs, v. DON J. WAGONER and WAGONER MEDICAL CENTER, L.L.C., Defendants.	CAUSE NO.: 2:17-CV-478-TLS

OPINION AND ORDER

This matter is before the Court on Defendants Don J. Wagoner and Wagoner Medical Center, L.L.C.'s Motion for Summary Judgment [ECF No. 169]. This lawsuit stems from the Defendants' presentation of around 5,217 claims to Indiana Medicaid with the CPT Code 80101 for testing the urine samples of their pain medication patients with drug screening test kits, which identify the presence or absence of nine or more drug classes. *See* Third Am. Compl., ECF No. 83.

The Plaintiff, United States of America (the Government), brings three federal claims under the False Claims Act (FCA), 31 U.S.C. §§ 3729–33: the first claim is based on the Defendants' presentation of around 5,217 false and fraudulent claims to Indiana Medicaid (Count 1), the second claim is based on the Defendants' presentation of false records or statements to Indiana Medicaid (Count 2), and the third claim is based on the Defendants' receipt of an overpayment from Indiana Medicaid of around $1,030,162.03 caused by the submission to Indiana Medicaid of the around 5,217 false and fraudulent claims by the Defendants without

repayment (Count 3). *Id.*[1] The Plaintiffs United States of America and the State of Indiana also bring joint claims under common law for payment by mistake (Count 4) and unjust enrichment (Count 5). *Id.* Further, the State of Indiana brings three claims under the Indiana Medicaid False Claims Act for presentation of false claims (Count 6), false statements material to false claims (Count 7), and false statements material to an obligation to pay money (Count 8).[2] Plus, the State of Indiana brings claims for improper receipt of Medicaid payments (Count 9) and for being a victim of a property crime (Count 10) under Indiana law.[3]

The Defendants filed their Motion for Summary Judgment [ECF No. 169] on October 20, 2023. The Plaintiffs filed their response [ECF No. 178] on December 22, 2023. The Defendants then filed their reply [ECF No. 182] on January 26, 2024. For the reasons set forth below, the Court grants in part and denies in part the Defendants' Motion.

SUMMARY JUDGMENT STANDARD

Summary judgment is warranted when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The movant may discharge this burden by "either: (1) showing that there is an absence of evidence supporting an essential element of the non-moving party's claim; or (2) presenting affirmative evidence that negates an essential element of the non-moving party's claim." *Hummel v. St. Joseph Cnty. Bd. of Comm'rs*, 817 F.3d 1010, 1016 (7th Cir. 2016) (citation omitted). In response, the non-movants "must make a sufficient showing on every element of [their] case on which [they] bear[] the burden of proof; if [they] fails to do so, there is no issue for trial." *Yeatts v. Zimmer Biomet Holdings, Inc.*, 940 F.3d 354, 358 (7th Cir. 2019)

[1] Count 1 is brought under 31 U.S.C. § 3729(a)(1)(A), Count 2 is brought under 31 U.S.C. § 3729(a)(1)(B), and Count 3 is brought under 31 U.S.C. § 3729(a)(1)(G).
[2] Count 6 is brought under Ind. Code § 5-11-5.7-2(a)(1), Count 7 is brought under Ind. Code § 5-11-5.7-2(a)(2), and Count 8 is brought under Ind. Code § 5-11-5.7-2(a)(6).
[3] Count 9 is brought under Ind. Code § 12-15-23 and Count 10 is brought under Ind. Code § 34-24-3-1.

(citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). In ruling on a motion for summary judgment, a court must construe all facts and draw all reasonable inferences in the light most favorable to the nonmoving party. *Id.* (citation omitted). A court's role "is not to sift through the evidence, pondering the nuances and inconsistencies, and decide whom to believe. The court has one task and one task only: to decide, based on the evidence of record, whether there is any material dispute of fact that requires a trial." *Waldridge v. Am. Hoechst Corp.*, 24 F.3d 918, 920 (7th Cir. 1994) (citations omitted).

MATERIAL FACTS[4]

A. CPT Code 80101

During 2008, Defendants Don J. Wagoner and Wagoner Medical Center, L.L.C., began processing urine drug tests. Pl. Ex. O, 22:9–14, ECF No. 179-15. From January 1, 2011 to January 13, 2013, when the Defendants sought reimbursement from Indiana Medicaid for processing urine drug testing for the 5,217 claims at issue, the Defendants used CPT Code 80101. *See* Third Am. Compl., Exs. 1B, 1C, 1D, ECF Nos. 83-2, 83-3, 83-4. The Defendants' medical billing and coding expert, Cristine Miller, testified that the American Medical Association's (AMA) *CPT* is authoritative on the use of CPT Codes. Def. Reply Ex. 3, 92:5–8, ECF No. 183-3.

The 2011 AMA *CPT* provides several relevant codes for billing for urine drug tests. CPT Code 80100 is for "Drug screen, qualitative; multiple drug classes chromatographic method, each procedure." Pl. Ex. T, p. 404, ECF No. 179-20. CPT Code 80101, which was used by the Defendants, is used by a provider to bill for processing a urine drug test with a "single drug class

[4] The facts offered by the parties are considered only to the extent they are supported by the properly cited evidence of record. Additionally, the parties request that the Court take judicial notice of Howard Superior Court Case No. 34D01-1304-FA-277, *Indiana v. Donald Wagoner*. Pursuant to Federal Rule of Evidence 201, the Court takes judicial notice of the electronic dockets for the Indiana courts, which are available at https://public.courts.in.gov/mycase/.

method (eg, immunoassay, enzyme assay), each drug class." *Id.* However, CPT Code 80101 contains additional language that instructs, "(For qualitative analysis by multiplexed drug screening kit for multiple drugs or drug classes, use 80104)." *Id*. CPT Code 80104 then immediately follows (before CPT Code 80102) and provides, "multiple drug classes other than chromatographic method, each procedure." *Id*. There is a notation at the end of the section after CPT Code 80103 indicating that CPT Code 80104 "is out of numerical sequence." *Id.*

The Defendants performed the urine drug tests at issue with test kits by Wondfo, which are an immunoassay and are also multiplexed drug screening kits that test for multiple drug classes. *See* Pl. Ex. B, 77:20–24, ECF No. 179-2; Pl. Ex. U, p. 1, ECF No. 179-21; Def. Reply Ex. 6, ECF No. 183-6, p. 2 of 14.

B. Medical Necessity

The Government's clinical expert, Dr. Timothy King, explained in his Addendum Report that the AMA defines "medical necessity" as

> [h]ealth care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.

Pl. Ex. M, p. 3, ECF No. 179-13 (quoting AMA Policyfinder, Medical Review, Definitions of "Screening" and "Medical Necessity" H-320.953, https://policysearch.ama-assn.org/policyfinder/detail/H-320.953?uri=%2FAMADoc%2FHOD.xml-0-2625.xml (last visited Sept. 5, 2024)). He testified that the AMA definition of medical necessity

> means that a particular procedure or—or test was done so as to inform patient care. In other words, it's for the purpose of addressing, refining treatment or—or diagnosis on a patient. It's for the patient's benefit. If it doesn't inform patient care, then the test does not meet the test of medical necessity.

Pl. Ex. D, 157:4–11, ECF No. 179-4. Dr. King also testified that

> it is important that—that any inconsistent results be not only documented in the medical chart, very plainly documented, but also acknowledged. And—and clinical action of some sort taken and acknowledged and documented. Otherwise, the test is not only deemed to be medically unnecessary, but also lacks any contribution to patient safety and patient care.

Id., 169:8–15. He said, "Bottom line is, inconsistent urine drug tests, as we're talking about here, regardless of the reason for the inconsistency, must never be ignored, must always be addressed, and documentation provided." *Id*., 169:15–18; *see also* Pl. Ex. M, p. 2 (citing Howard A. Heit & Douglas L Gourlay, *Urine Drug Testing in Pain Medicine*, 27 J. Pain & Symptom Mgmt. P260 (2004)).

Dr. King reviewed the medical records of the Defendants' patients to determine whether a sample of 88 of the urine drug tests performed were medically necessary. Pl. Ex. M., p. 1.[5] Of the 88 urine drug tests of the Defendants' patients, he concluded that 80 were medically unnecessary. *Id*. Dr. King stated that this was because the Defendants "failed to act in the manner of a prudent physician; failed to act according to accepted standards of medical practice; and failed to use urine drug testing for the benefit of the patient." *Id*., p. 3. He also stated that "[u]rine drug testing, particularly in the care of patients treated for chronic pain, generally lacked medical necessity." *Id*.

At his deposition, Dr. King was asked by the Defendants' counsel about his review of the urine drug tests' clinical worth, "[A]re you looking at it from a . . . more holistic approach of a course of treatment . . . or are you looking more of a one-to-one scenario of, did it inform the decision-making of a single encounter, or is it both?" Def. Mot. Exclude Ex. 1, 158:5–11, ECF No. 168-1. Dr. King responded, "No, it's the latter. . . . We don't practice medicine on a generalized basis." *Id*., 158:12–15. He said his review of the Defendants' patient files was based

[5] The parties stipulated that the Defendants' 88 claims that were submitted to Indiana Medicaid for reimbursement for urine drug tests are a statistically valid random sample of the 5,217 claims at issue. *See* Def. Ex. 2, ¶ 4, Ex. A, ECF No. 171-2.

on the belief that the "standard of care requires that if a urine drug screen, a presumptive point-of-care done at the time that the patient is in the office is performed, then that result will be available to inform clinical decision-making at that visit." *Id.*, 159:17–21.

On the other hand, the Defendants' clinical expert, Dr. James Patrick Murphy, stated in his report that "[t]he term 'medical necessity' is a business tool used by the third-party payers. It has no standardized meaning." Def. Reply Ex. 10, p. 4, ECF No. 183-10. He testified that "if the patient has a condition for which ordering that test is . . . medically necessary, [then] it's a medically necessary test." Def. Mot. Exclude, Ex. 2, 135:16–18, ECF No. 168-2.

Dr. Murphy also testified that, in applying that standard, what factored into his decision-making as to whether the drug tests at issue were medically necessary was that "[he] was looking . . . for the diagnosis for . . . the justification for ordering the test." Def. Mot. Exclude, Ex. 2, 129:14–16. Dr. Murphy agreed that urine drug tests are just one piece of the whole puzzle to use in making treatment decisions. *Id.*, 143:12–17. He based his articulation of the standard for medical necessity on the definition by the AMA and on national guidelines for urine drug tests, such as those from the Centers for Disease Control and Prevention and the American Academy of Pain Medicine. Def. Reply Ex. 10, pp. 6, 12, 13–14.

Dr. Murphy testified that he reviewed the medical files of the sample of 88 of the Defendants' patients and he "saw no urine drug screens in any of the files that led [him] to believe that they were not medically necessary." Def. Mot. Exclude, Ex. 2, 126:15–17. Dr. Murphy concluded after reviewing the Defendants' medical records that "the patients had conditions where they were on medications that would make a drug screen medically necessary." *Id.*, 127:10–12. In his report, Dr. Murphy explained that he "examined the Defendants' use of drug tests and came to the conclusion that drug tests ordered satisfied the AMA's definition of medical necessity." Def. Reply Ex. 10, p. 6.

C. Damages

The Government bases its damages calculation on four exhibits attached to the Third Amended Complaint. Third Am. Compl., Exs. 1A, 1B, 1C, 1D. Exhibits 1B, 1C, and 1D each includes the claim, claim number, date of service, paid amount, procedure code, modifier, quantity, and total paid to the Defendants from January 1, 2011, through January 13, 2013. *See id*., Exs. 1B, 1C, 1D. Exhibit 1B shows that $277,534.47 total was paid by Indiana Medicaid, Exhibit 1C shows that $665,027.03 total was paid by Hoosier Healthwise, and Exhibit 1D shows that $195,977.24 total was paid by the Healthy Indiana Program. *Id*., Exs. 1B, p. 36, 1C, p. 69, 1D, p. 20.[6] Exhibit 1A shows a chart with the total number of claims submitted by the Defendants to Indiana Medicaid, Hoosier Healthwise, and the Healthy Indiana Program equaling 5,217 claims and totaling $1,138,538.74 in payments. *Id*., Ex. 1A. That chart also shows that, of the $1,138,538.74 total paid, $108,376.71 was correctly billed leaving an overpayment of $1,030,162.03. *Id*.

ANALYSIS

The three issues before Court on the Defendants' motion for summary judgment are whether under the False Claims Act (FCA), 31 U.S.C. §§ 3729–33, the Government has shown: (1) that the Defendants presented false claims, records, or statements to the Government in connection with billing Indiana Medicaid using CPT Code 80101 for urine drug screen testing, and the Defendants knew so, (2) that those drug screens lacked medical necessity, and the Defendants knew so, and (3) damages. The Court first addresses the Government's FCA claims

[6] Indiana Medicaid programs include Hoosier Healthwise and Healthy Indiana Program. *See* Indiana Medicaid for Members, Programs, https://www.in.gov/medicaid/members/member-programs/ (last visited Sept. 11, 2024).

based on the Defendants' use of CPT Code 80101 and a lack of medical necessity and then addresses damages.

A. Use of CPT Code 80101 and Lack of Medical Necessity

There are two types of False Claims Act violations alleged by the Government in this case. For the first, a defendant violates the False Claims Act when it "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A defendant also violates the False Claims Act when it "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id*. § 3729(a)(1)(B). To establish a prima facie case for a violation based on a false or fraudulent claim or a false record or statement under the FCA, the plaintiff "generally must prove (1) that the defendant made a [claim, record, or] statement in order to receive money from the government; (2) that the [claim, record, or] statement was false; and (3) that the defendant knew the [claim, record, or] statement was false." *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 822 (7th Cir. 2011).

As a result, "a False Claims Act case requires proof of falsity, knowledge, materiality (meaning whether the alleged misrepresentations had the natural tendency to influence the payment or receipt of funds), and the involvement of federal funds." *United States ex rel. Heath v. Wis. Bell, Inc.*, 92 F.4th 654, 659 (7th Cir. 2024). But "[w]hat matters for an FCA case is whether the defendant knew the claim[, record, or statement] was false." *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 743 (2023).

In this case, the Defendants only move for summary judgment on the elements of falsity and knowledge on the Government's FCA claims based on seeking reimbursement from Indiana Medicaid using CPT Code 80101 and based on a lack of medical necessity; the Defendants do not seek summary judgment based on the elements of materiality or federal funds for these FCA

claims or on the FCA claims based on their use of Modifier 91. For the claims based on reimbursement using CPT Code 80101 the Government must demonstrate that the CPT Code the Defendants used to bill Indiana Medicaid for the drug screening tests at issue was false and that the Defendants knew so. Because the Government has offered sufficient evidence, the FCA claims based on the CPT Code survive summary judgment for the reasons set forth below. As for the claims based on lack of medical necessity, the Government must demonstrate that the drug screening tests were not medically necessary and that the Defendants knew so. Because the Government has not offered sufficient evidence, the FCA claims based on a lack of medical necessity do not survive summary judgment for the reasons set forth below.

1. CPT Code 80101

In this case, it is undisputed that the 2011 *CPT* is authoritative on the CPT Codes at issue. It is also undisputed that the Defendants performed the qualitative analysis of urine samples by using multiplexed drug screening kits for multiple drug classes that were an immunoassay and that the Defendants billed Indiana Medicaid for those services using CPT Code 80101—a CPT Code for a urine drug test that is an immunoassay.

However, in the Second Amended Complaint, the Government alleges that the Defendants falsely used CPT Code 80101 instead of the correct code—CPT Code 80104—with knowledge of that falsity. Here, the Defendants contend that the language of CPT Code 80104 itself means that it is the incorrect CPT Code to use for reimbursement for their urine drug screening services because their kits used a "chromatographic method" and CPT Code 80104 is for tests that use a method "other than a chromatographic method." The Defendants also contend that, even if their kits did not use a "chromatographic method," there is no evidence that the Defendants knew so. In response, the Government asserts that the language of CPT Code 80101, directing that "[f]or qualitative analysis *by multiplexed screening kit for multiple drugs or drug*

classes, use 80104," means that CPT Code 80104 is the correct code for providers to use when seeking reimbursement for performing drug screens by a "qualitative analyses by multiplexed screening kit," such as those that the Defendants performed. Thus, according to the Government, the Defendants falsely used CPT Code 80101 when seeking reimbursement for the drug screens at issue with knowledge of that falsity. For the reasons set forth below, the Court finds that the Government has demonstrated a genuine dispute of material fact on the issues of whether the Defendants falsely used CPT Code 80101 in billing Indiana Medicaid for their urine drug screen testing services and whether the Defendants had knowledge of that falsity.

For CPT Code 80101, the AMA's *CPT* provides that when seeking reimbursement "[f]or qualitative analysis by multiplexed drug screening kit for multiple drugs or drug classes, use 80104." Pl. Ex. T, p. 404. When interpreting a given provision, courts begin with the plain language, and where that is "unambiguous" "the inquiry ceases." *Preston v. Midland Credit Mgmt., Inc.*, 948 F.3d 772, 780 (7th Cir. 2020) (quoting *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016)); *see Nielen-Thomas v. Concorde Inv. Servs., LLC*, 914 F.3d 524, 528 (7th Cir. 2019) ("If the text is clear, [the] [courts] end [the] inquiry here as well."); *Silvernail v. Ameritech Pension Plan*, 439 F.3d 355, 358 (7th Cir. 2006) ("The basic rule in statutory interpretation is that plain statutory language governs." (quoting *Nestle Holdings, Inc. v. Cent. States, S.E. & S.W. Areas Pension Fund*, 342 F.3d 801, 804 (7th Cir. 2003))).

Consequently, the Court agrees with the Government that the plain language of CPT Code 80101 instructs providers billing for a "qualitative analysis by multiplexed drug screening kit for multiple drugs or drug classes," such as the Defendants here, to "use 80104" without qualification. Because the plain language of CPT Code 80101 is unambiguous, neither the Court nor providers need to look to the language of CPT Code 80104 itself for whether to use CPT

Code 80104 when billing for drug screening using multiplexed screening kits as directed in CPT Code 80101. *See id*.

Nevertheless, the Defendants ignore the provision in CPT Code 80101 directing that CPT Code 80104 be used for "qualitative analysis by multiplexed drug screening kit for multiple drugs or drug classes," essentially contending that the language contained in CPT Code 80104 itself is all that matters. For CPT Code 80104, the *CPT* states that the code is used for billing for drug screening testing for "multiple drug classes *other than chromatographic*." According to the Defendants, if a provider performs drug screens with kits that use a "chromatographic method," CPT Code 80101 is the correct code, and CPT Code 80104 is incorrect because of the phrase "other than chromatographic." But ignoring the unqualified provision in CPT Code 80101 directing the use of CPT Code 80104 for a "multiplexed drug screening kit" would render the language of CPT Code 80101 superfluous or meaningless. And, "it is a cardinal principal" that a provision "ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001); *see GNB Battery Techs., Inc. v. Gould, Inc.*, 65 F.3d 615, 622 (7th Cir. 1995) ("When interpreting a contract, [the court] cannot read terms into the language that are not expressly stated, nor will [the court] ignore terms that are explicitly written therein. A contractual interpretation that gives reasonable meaning to all of the terms in an agreement is preferable to an interpretation which gives no effect to some terms." (cleaned up)).

Also, the Defendants have not pointed to any expert testimony or other evidence indicating that it is incorrect to use CPT Code 80104 to bill for a "qualitative analysis by multiplex drug kit for multiple drugs or drug classes" that is an "immunoassay," given that "immunoassay" is listed as an example of "single drug class method" for CPT Code 80101. Consequently, based on the plain language of CPT Code 80101 as analyzed above, the language

of CPT Code 80104 is irrelevant to the determination of whether to use CPT Code 80104 when billing for qualitative analysis of urine samples by a "multiplexed screening kit for multiple drugs or drug classes" that is an "immunoassay." Thus, the Court need not address the parties' arguments on whether the record establishes that the Defendants' drug screening test kits used a chromatographic method, whether CPT Code 80104 is an incorrect CPT Code for a test kit that uses a chromatographic method, or whether the Defendants knew that the drug screening kits did not use a chromatographic method.

Also, although the Defendants assert that that only way to establish overpayment is for the Government to conduct an audit, and the Government has not, the Defendants do not cite to any pertinent legal authority standing for the proposition that an audit is the only way to establish overpayment. Consequently, any arguments on the lack of a government audit are waived and unavailing. *See Mahaffey v. Ramos*, 588 F.3d 1142, 1146 (7th Cir. 2009) ("Perfunctory, undeveloped arguments without discussion or citation to pertinent legal authority are waived.").

Accordingly, the Court concludes that a genuine dispute of material fact remains as to whether the Defendants falsely used CPT Code 80101 with knowledge of that falsity in billing Indiana Medicaid. Therefore, summary judgment is denied on the issues of falsity and knowledge of the falsity based on the Defendants' use of CPT Code 80101 for the Government's FCA claims brought under § 3729(a)(1)(A) and § 3729(a)(1)(B). Because the Defendants did not move for summary judgment on the claims based on the Defendants' use of Modifier 91, whether the Defendants use of Modifier 91 is a violation of the FCA and any corresponding damages also remain issues for trial.

2. Medical Necessity

The Defendants also seek summary judgment on the Government's claim that they submitted claims to Indiana Medicaid for reimbursement for urine drug tests that were not

medically necessary, thereby constituting false claims under the FCA. Indiana Medicaid conditions payment for service, such as the performance of a urine drug test, on "medical necessity," Ind. Code §§ 12-15-21-3(3), (4)(B)—meaning a violation occurs if a provider requests reimbursement for a service that is not a medical necessity. *Cf. Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1114 (9th Cir. 2020) ("Because medical necessity is a condition of payment, every Medicare claim includes an express or implied certification that treatment was medically necessary. Claims for unnecessary treatment are false claims."). Indiana Medicaid defines "medical necessity" as "[t]he evaluation of health care services to determine if they are medically appropriate and necessary to meet basic health needs; consistent with the diagnosis or condition and rendered in a cost-effective manner; and consistent with national medical practice guidelines regarding type, frequency, and duration of treatment." Indiana Medicaid for Members, Understanding Terms, https://www.in.gov/medicaid/members/member-resources/understanding-terms/ (last visited Sept. 11, 2024); *see Thie v. Davis*, 688 N.E.2d 182, 187 (Ind. Ct. App. 1997) ("Absent a federal definition of medical necessity, the responsibility for defining medical necessity is left to the states." (citing *Rush v. Parham*, 625 F.2d 1150, 1155 (5th Cir. 1980))).

Consequently, to show that under the FCA the Defendants submitted false claims to Indiana Medicaid on the basis that the claims lacked medical necessity, the Government must establish that the urine drug tests performed by the Defendants were not a medical necessity as defined by Indiana Medicaid. *See United States v. Molina Healthcare of Ill., Inc.*, 17 F.4th 732, 742 (7th Cir. 2021) (explaining that under an express false certification theory, the plaintiff must show an "express false certification—that is, an affirmative misstatement of compliance with a statute, regulation, or other contractual obligation to obtain payment from the government—as a basis of liability" (citing *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*,

764 F.3d 699, 710–11 (7th Cir. 2014))); *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 187 (2016) (holding that an implied false certification theory can provide a basis for liability, explaining that "[w]hen . . . a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided"); *see also United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006) ("Claims are not 'false' under the FCA unless they are furnished in violation of some controlling rule, regulation[,] or standard." (citations omitted)). For the reasons set forth below, the Court concludes that the Government offers insufficient evidence to create a genuine dispute of fact that the urine drug tests performed by the Defendants lacked medical necessity.

The parties mainly offer their experts' differing interpretations of the AMA's definition of medical necessity as applied to urine drug tests, which is insufficient to create a genuine dispute of fact. In the Second Amended Complaint, the Government alleges that the urine drug tests performed by the Defendants lacked medical necessity because the Defendants did not use the test results to monitor and enforce the use of controlled substances or otherwise apply the results to patient care. In support of the instant motion, the Defendants offer evidence that urine drug tests are a medical necessity so long as "the patient has a condition for which the test is necessary." According to the Defendants' expert, Dr. Murphy, that standard is consistent with the AMA definition of medical necessity and other national guidelines. Based on those definitions, Dr. Murphy concluded that the medical necessity of a urine drug test depends on the diagnosis and the justification for ordering the test. Dr. Murphy also testified that he reviewed a sample of 88 of the Defendants' patient files applying that standard and "saw no urine drug screens in any of the files that led [him] to believe that they were not medically necessary."

In its response brief, the Government does not acknowledge or otherwise address any of that evidence highlighted by the Defendants, and so it remains unrefuted. What the Government offers instead is a standard for the medical necessity of urine drug tests from a 2004 medical journal that the Government's expert, Dr. King, interpreted as requiring the provider to demonstrate a clear relationship between the urine drug test results and the *subsequent* treatment actions by the provider. The Government offers Dr. King's testimony applying that standard to conclude that, in 80 out of 88 of the Defendants' patients sampled, the Defendants' urine drug tests were not medically necessary.

However, the Government offers no evidence or argument that the standard for the medical necessity of urine drug tests that Dr. King applied in his review of the Defendants' patient files was the standard that Indiana Medicaid expected providers to adhere to or that the standard Dr. Murphy applied contravenes Indiana Medicaid's definition of medical necessity. Instead, without citation to any legal authority, the Government appears to reason that, because there is a standard for the medical necessity of urine drug tests that its expert formulated based on a 2004 medical journal article, providers—such as the Defendants—may not follow any other standard for medical necessity when seeking urine drug test reimbursement from Indiana Medicaid.

Accordingly, the Court finds that the dispute here on medical necessity grows out of the parties' experts applying different standards for the medical necessity of urine drug tests. The Defendants' expert, Dr. Murphy, applied a standard based on the patient's diagnosis whereas the Government's expert, Dr. King, applied a standard based on how the provider uses the test results. And this dispute ultimately stems from the lack of evidence or argument that—at the time the Defendants sought reimbursement for the urine drug tests at issue—Indiana Medicaid had adopted the standard applied by either expert, Indiana Medicaid had adopted any other

standard for the medical necessity of urine drug tests, or either party's standard contravenes Indiana Medicaid's definition of medical necessity.

Thus, the Court concludes that, even viewing the evidence in the light most favorable to the Government, the evidence at most only shows a disputed issue as to the applicable standard for the medical necessity of urine drug testing—a disputed legal question. That is not enough to support a reasonable inference that the medical necessity of the urine drug testing performed by the Defendants was false within the meaning of the False Claims Act, because "differences in interpretation growing out of a disputed legal question are . . . not false under the FCA." *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999). Therefore, the Court grants summary judgment in favor of the Defendants on the Government's § 3729(a)(1)(A) and § 3729(a)(1)(B) claims that are based on a lack of medical necessity. Consequently, the Court need not address the parties' arguments on whether the Defendants knew that their urine drug tests lacked medical necessity.

B. Damages

Finally, the Defendants move for summary judgment on the Government's allegation that it incurred damages connected to its § 3729(a)(1)(A) and § 3729(a)(1)(B) claims, arguing that the Government lacks any evidence establishing its damages from the Defendants' alleged false claims, records, or statements.

The Government is seeking the "overpayment to which Defendants were not entitled of approximately $1,030,162.03" that resulted from the "Defendants submitting 5,217 excess false and fraudulent claims to Indiana Medicaid." Pl. Br. 21, ECF No. 178. In this case, the Government's alleged damages are "three times the total loss sustained by the government because of the[] [Defendants'] false claim(s)[, records, or statements]." *Stop Ill. Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899, 906 (7th Cir. 2024) (quoting 31 U.S.C. § 3729(a)(1)).

Additionally, the FCA "imposes a civil penalty between $5,000 and $10,000 for each claim, adjusted for inflation." *Id*. Thus, to recover the amount of money that the Government paid as a result of the Defendants' alleged false claims, records, or statements, the Government must show "the number and [dollar] amount of false claims that the defendants submitted to the government" during the relevant time period. *Id*. The Government may establish such evidence using a spreadsheet containing enough details to permit the calculation of the damages using the formula in 31 U.S.C. § 3729(a). *See id*. at 909–10.

The Defendants argue that the Government cannot show that it suffered damages from the Defendants' allegedly false claims, records, or statements for at least two reasons. First, the Defendants assert that the "[Government] [has] done absolutely nothing to substantiate this allegation or offer evidentiary support for this amount [of $1,030,162.03]." Def. Br. 10–11, ECF No. 170. According to the Defendants, the problem is that the Government did not offer evidentiary support from a coding expert that reviewed whether overpayment occurred. *See id*. at 11. However, the Defendants fail to cite to any legal authority standing for the proposition that the Government must provide evidence of overpayment from a coding expert to establish damages.[7]

[7] For the first time in their reply brief, the Defendants cite the *CMS Program Integrity Manual* to support their assertion that the Government needs a coding expert to review the patient medical records to establish damages. They say that "[t]he CMS Program Integrity Manual requires that when a contractor is engaged by the government to identify overpayments, such overpayments must be determined through a 'coding review conducted by a Certified Professional Coder or Certified Coding Specialist with an active certification.'" Def. Reply 13, ECF No. 182. However, the Defendants do not explain how that leads to the conclusion that a coding expert's review of medical records is the only way for the Government to establish overpayment in this case. Further, the Defendants do not explain why a review of medical records is necessary for establishing damages based on the Government's theory of the Defendants' liability in this case, which stems from the type of drug screen kits the Defendants used and their improper use of the corresponding CPT Code and Modifier 91. Because the Defendants do not provide these explanations or cite to any legal authority in support of their assertion, the Court finds their assertion unavailing. *See Mahaffey*, 588 F.3d at 1146.

Also, the Defendants contend that the "[Government] [has] neglected to offer any other kind of evidence that supports their request for damages." *Id*. But, as highlighted by the Government, it has provided spreadsheets summarizing the claims that the Defendants submitted to Medicaid, Hoosier Healthwise, and the Healthy Indiana using CPT Code 80101, including the claim number, date of service, dollar amount paid, and quantity per claim totaling $1,138,538.74. *See* Third Am. Compl., Exs. 1A, 1B, 1C, 1D. And, the Defendants provide no explanation for why these spreadsheets are insufficient for calculating the damages using the formula in 31 U.S.C. § 3729(a).

Second, the Defendants assert that "there is absolutely no evidence that Defendants received an overpayment based upon their submission of claims using [CPT Code 80101]." Def. Br. 11. However, there is evidence in the record showing a chart accounting for the amounts that the Defendants correctly billed for urine drug screen tests to Indiana Medicaid, Hoosier Healthwise, and Healthy Indiana using CPT Code 80101, which totals $108,376.71 and results in an overpayment of $1,030,162.03—the damages sought by the Government. And, again, the Defendants fail to explain why this chart combined with the spreadsheets are insufficient for calculating the damages using the formula in 31 U.S.C. § 3729(a).

Therefore, the Court concludes that there is sufficient evidence for the fact finder to find that the Government is owed damages.

CONCLUSION

Based on the foregoing, the Court hereby GRANTS in part and DENIES in part Defendants Don J. Wagoner and Wagoner Medical Center, L.L.C.'s Motion for Summary Judgment [ECF No. 169], granting summary judgment in favor of the Defendants on the Government's claims in Counts 1 and 2 that are based on a lack of medical necessity, and denying summary judgment on the Government's claims in Counts 1 and 2 that are based on the

Defendants' use of CPT Code 80101 and on damages. Because the Defendants did not move for summary judgment on the Government's claims in Counts 1 and 2 that are based on inaccurate billing stemming from the Defendants' use of Modifier 91, whether the Defendants' use of Modifier 91 is a violation of the FCA remains an issue for trial. Because the Defendants did not move for summary judgment on Counts 3–10, those claims remain for trial, too.

The Court ORDERS the parties to file a joint status report or before October 17, 2024, regarding their willingness to engage in a settlement conference before a Magistrate Judge. A trial date will be set under a separate order.

SO ORDERED on September 17, 2024.

s/ Theresa L. Springmann
JUDGE THERESA L. SPRINGMANN
UNITED STATES DISTRICT COURT